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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/603,320 06/26/00 BURZYNSKI

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HM22/1024

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EXAMINER

BAHAR, M

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/24/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

**Application No.**

09/603,320

**Applicant(s)**

BURZYNSKI, STANISLAW R.

**Examiner**

Mojdeh Bahar

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-18 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
  2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
  3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 8 and 16 drawn to a method of treatment or inhibition of hypercholesterolemia or hypertriglyceridemia comprising the step of administering a composition comprising a therapeutically effective amount of a compound of either formula I, III or IV classified in Class 514 and subclasses 277, 564, 513, 438, 568 for example.
- II. Claims 5-7 and 9-15 drawn to a method of treatment or inhibition of hypercholesterolemia or hypertriglyceridemia comprising the step of administering a composition comprising a therapeutically effective amount of two or more compounds selected from formulas I, III or IV classified in Class 514 and subclasses 277, 564, 513, 438, 568 for example.
- III. Claim 17, drawn to a pharmaceutical composition for treatment or inhibition of hypercholesterolemia or hypertriglyceridemia comprising a therapeutically effective amount of a compound of either formula I, III or IV classified in Class 514 and subclasses 277, 564, 513, 438, 568 for example.
- IV. Claim 18, drawn to a pharmaceutical composition for treatment or inhibition of hypercholesterolemia or hypertriglyceridemia comprising a therapeutically effective amount of at least two of the compounds in

formulas I, III and IV classified in Class 514 and subclasses 277, 564, 513, 438, 568 for example.

The inventions are distinct, each from the other because:

Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP §806.04, MPEP §808.01). In the instant case Group I has a different mode of operation than Group II. Group I is drawn to a method of treating hypercholestroemia or hypertriglyceridemia which operates by administering a composition comprising one of the compounds in formulas I, III and IV; whereas Group II is drawn to a method which operates by the administration of two or more of the compounds in formulas I, III and IV. Groups III and IV are drawn to two distinct pharmaceutical compositions with different modes of operation. Group III operates by the administration of a composition comprising a single compound of either formulas I, III or IV. In contrast, Group IV is drawn to a composition operating by the administration of at least two of the compounds in formulas I, III and IV. Therefore, Groups III and IV have different modes of operation.

Inventions in Groups I and III as well as Groups II and IV are related as product and process of use. Group III teaches a composition comprising only one of the compounds in formulas I, III and IV and Group I recites a method of treating hypercholestroemia or hypertriglyceridemia by administering the composition recited in Group III. Similarly, while Group IV teaches a composition comprising at least two of the compounds in formulas I, III and IV, Group II describes a method of treating

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hypercholesterolemia or hypertriglyceridemia by administering the composition taught in Group IV. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antihypercholesterolemic and antihypertriglyceridemic processes for using the products as claimed can be practiced with materially different products such as one containing any HMG CoA Reductase inhibiting agents or Nicotinic acid derivatives.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Specie Election***

Claims 1-9 and 17-18 are generic to a plurality of disclosed patentably distinct species comprising substitutions possible on  $R^2$  and M to the core structure represented by formulas I, III and IV.

The species comprising  $R^2$  are as follows:

- (a) a specified  $C_{6-12}$  aryl: benzene, pyridine, toluene, naphthalene, etc.
- (b) a specified substituted aryl: benzoylbromide, naphthylbenzene, etc.

The species comprising M are as follows:

- (a) a specified naturally occurring amino acid: alanine, histidine, tryptophan, etc.

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- (b) a specified C<sub>6-12</sub> aryl: benzene, pyridine, toluene, naphthalene, etc.
- (c) diethanolamine or ammonium, cyclohexylamine
- (d) Hydrogen, sodium, potassium, lower alkyl, cycloalkyl.

These claims encompass species that are so diverse and unrelated that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents. To illustrate this diversity, consider the following examples: a compound of formula I, having an R<sub>2</sub> substituent pyridine and where M is hydrogen, is classified in Class 514 subclass 277. A compound of formula I, having an R<sub>2</sub> substituent which is a benzene ring and where M is hydrogen, is classified in Class 514 subclass 564. A compound of formula I, where M is alanine (a naturally occurring amino acid) and R<sub>2</sub> substituent is benzene, is classified in Class 514 subclass 513. A compound of formula IV where M is hydrogen and R<sub>2</sub> is thiophene is classified in class 514 subclass 438. A compound of formula IV where M is ammonium and R<sub>2</sub> is benzene is classified in class 514 subclass 568. Please note that for all these examples R and R<sub>1</sub> are Hydrogen and n=1.

Therefore, the diversity of species in claims 1-9 and 17-18 requires a search of many different subclasses, 277, 564, 513, 438, 568, etc., which constitutes a burden to the office. Applicant is advised that the response to this requirement must include an identification of the species that is consonant with the requirement set forth in 35 U.S.C. 121 as well as a listing of all claims readable thereon.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

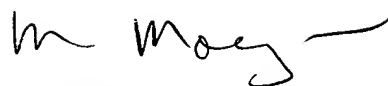
Mojdeh Bahar  
Patent Examiner

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October 6, 2000

A handwritten signature in black ink, appearing to read "m Moezie", with a long horizontal flourish extending to the right.

MINNA MOEZIE, J.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600